REMARKS

Claims 1-8, 22, 23, 25, 61-63, and 65-75 are currently pending in this application. Claims 9-21, 24, 26-60 and 64 were previously cancelled without prejudice or disclaimer. Applicant respectfully reserves the right to prosecute the subject matter of the cancelled claims in one or more continuation or divisional applications.

Rejections

Rejections under 35 U.S.C. § 103

A. Claims 1-8, 22, 61-63 and 65-70 were rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Panis *et al*, in view of Fretz *et al*, European Patent No. 0147236, Cino *et al* (U.S. Patent No. 5,527,702) and Goodrich Jr., *et al* (U.S. Patent No. 5,800,978). According to the Office Action, the claims were deemed *prima facie* obvious.

Applicant respectfully disagrees and traverses this rejection.

As stated in Applicant's prior response, in order to establish a *prima facie* case of obviousness, three basic criteria must be met.

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991), MPEP §§ 2142, 2143.

The cryopreservation recovery method of independent claim 1, and each of the claims depending therefrom, requires at least each of the elements of obtaining cryopreserved plant cells, thawing the cryopreserved plant cells by heating the cells to a temperature above which the plant cells are not frozen to obtain thawed plant cells, serially washing the thawed plant cells in media having successively reduced concentrations of at least one cryoprotective agent, said media also containing a stabilizer, and removing the cryoprotective agent and recovering the thawed plant cells.

The Office Action states that "Panis *et al* teach that post-thaw washing of plant cells can be judiciously performed and that such technique removes any cryoprotectant that is present in the medium. Note page 340, lines 5-8" *See* Office Action, page 6, lines 5-7. Furthermore, the Office Action states that "Panis *et al* clearly suggest, if not teach, their method to be carried out in a medium having successively reduced concentrations of at least one cryoprotective agent since at page 341, noting figure 1, and at line 6, survival of thawed cells is maximized when cryoprotectant concentration is reduced." *Id* at 14-18.

The claimed subject matter is directed, in part, to washing the thawed plant cells in media having *successively reduced* concentrations of at least one cryoprotective agent. Applicant respectfully submits that Panis *et al* fail to teach this claim element, either expressly or impliedly. Applicant notes that the teachings of Panis *et al* on page 340, lines 5-8, referenced in the Office Action state "[a]fter 30 min in liquid nitrogen, the samples were thawed rapidly by placing the cryotubes in a waterbath of 40°C for about 1 min until most of the ice was melted. Post-thaw washing of cells to remove the cryoprotectant was done only when specified." See Panis *et al*, page 340, lines 5-8. Panis *et al* teach that the washing of cells to remove the cryoprotectant was done *only when specified.* Applicant submits that this disclosure does not teach a need for multiple washings of the thawed cells. Accordingly, Applicant submits that this disclosure does not teach or suggest, expressly or impliedly, washing the thawed plant cells in media having *successively reduced* concentrations of at least one cryoprotective agent, as is required by the claimed subject matter.

Likewise, Applicant submits that the teachings on page 341 of Panis *et al* do not teach or suggest, expressly or impliedly, washing the thawed plant cells in media having *successively reduced* concentrations of at least one cryoprotective agent, as is required by the claimed subject matter. Applicant submits that the teachings on page 341 are directed to the evaluation of the effects of differing concentrations of dimethylsulphoxide (DMSO) or other cryoprotectants in the freezing stage of the process set forth by Panis *et al*, and not to the subsequent step of washing the cells following thawing. Therefore, Applicant submits that this disclosure is irrelevant in teaching or suggesting washing the thawed plant cells in media having *successively reduced* concentrations of at least one cryoprotective agent.

Furthermore, on page 345 of Panis *et al* in the section entitled "Influence of post-thaw treatments", it is stated that

> [a]ccording to Benson and Withers (16) DMSO plays a protective role as a free radical scavenger in the post-thaw stabilization of cryopreserved cultures of Daucus carota. This, along with the observation that washing may impair recovery through, for example, deplasmolysis injury, led us to examine the effect of post-thaw washing in Musa. We found that removal of the cryoprotectant solution and its replacement by cryoprotectant-free liquid medium resulted in the complete loss of regrowth capacity, the cells becoming white (results not shown).

See Panis *et al*, page 345, lines 19-26. This discussion demonstrates that any washing steps of Panis *et al* are a one-step wash with a change to cryoprotectant free medium, and are not the washing of thawed plant cells in media having *successively reduced* concentrations of at least one cryoprotective agent, as is required by the claimed subject matter. The results obtained by Panis *et al* regarding the washing of thawed cells teach away from the combination of this reference with the other cited references to reach the claimed invention, since Panis *et al* state that "removal of the cryoprotectant solution and its replacement by cryoprotectant-free liquid medium resulted in the complete loss of regrowth capacity, the cells becoming white."

Furthermore, Applicant reiterates that there is no motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of Goodrich, Jr. *et al*, or to combine the teachings of Goodrich, Jr. *et al* with the previously cited references, in order to reach the claimed invention. According to the abstract of Goodrich, Jr. *et al*, this reference is generally directed to a process for freezing, including freeze-drying of cells, cell-membranes or cell-like materials using a cryoprotectant medium which stabilizes the cells or membranes for freezing or freeze-drying and allows for freezing or freeze-drying to be performed at -60°C or higher.

As stated in Applicant's prior response, since Goodrich, Jr. *et al* appears to be directed to techniques and compositions for the cryopreservation of animal and human cells, Applicant submits that one of ordinary skill in the art is not motivated by Goodrich, Jr. *et al* or the knowledge generally available to one of ordinary skill in the art, to modify the teachings of Goodrich, Jr. *et al* or to combine the teachings of Goodrich, Jr. *et al* with the previously cited references, in order to reach the claimed invention.

As is well known in the biological sciences, plant cells are differentiated from animal cells in part through the existence of a cell wall in plant cells. Due to the presence of a cell wall, one of ordinary skill in the art might reasonably expect cryopreservation techniques specific to

animal cells to perform differently when applied to plant cells, and therefore the person of ordinary skill would not rely on the teachings regarding the cryopreservation of animal cells (such as, for example, Goodrich, Jr. *et al*) for techniques adapted for use in the cryopreservation of plant cells.

This is supported by the Declaration of Michael E. Horn, Ph.D., currently of record, wherein it is stated that

> [w]hile cryopreservation of animal cultured cells is routine, cryopreservation of cultured plant cells has proven more difficult (*See*, the instant application, page 7, lines 24-26). Based on my experience, a person of ordinary skill in the art of plant cell culture would not view methods exemplified on human blood cells to be *per se* adaptable to plant cells with any reasonable expectation of success. Results from cryopreservation methods of animal cells are just not predicative of results obtained with plant cells.

See Horn Declaration, paragraph 10. As further stated in the Declaration, "it is unreasonable to suppose that any method that was designed for use using red blood cells, which do not have a cell wall, would be useful using plant cells or vice versa." *See* Horn Declaration, paragraph 11. Accordingly, Applicant submits that one of ordinary skill in the art is not motivated by Goodrich, Jr. *et al* or the knowledge generally available to one of ordinary skill in the art, to modify the teachings of Goodrich, Jr. *et al* or to combine the teachings of Goodrich, Jr. *et al* with the previously cited references directed to plant cells, in order to reach the claimed invention.

Furthermore, the Federal Circuit has stated that

> [s]ection 103 precludes...hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole. This court has provided further assurance of an 'as a whole' assessment of the invention under § 103 by requiring a showing that an artisan of ordinary skill in the art at the time of the invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner. In other words, the examiner or court must show some suggestion or motivation, before the invention itself, to make the new combination.

Ruiz v. A.B. Chance Co., 357 F.3D 1270, 1275, 69 U.S.P.Q.2D 1686, 1690 (Fed. Cir. 2004).

Accordingly, Applicant submits that the claims are not obvious over Panis *et al*, in view of Fretz *et al*, European Patent No. 0147236, Cino *et al* (U.S. Patent No. 5,527,702) and Goodrich Jr., *et al* (U.S. Patent No. 5,800,978). Therefore, Applicant respectfully requests

reconsideration and withdrawal of the rejection of claims 1-8, 22, 61-63 and 65-70 under 35 U.S.C. § 103(a).

B. Claims 23, 25 and 71-75 were rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Panis *et al*, in view of Fretz *et al*, European Patent No. 0147236 and newly cited Goodrich, Jr. *et al* (U.S. Patent No. 5,800,978).

Applicant respectfully disagrees and traverses this rejection.

Applicant respectfully submits that, for the same reasons set forth *supra* in section "A", claims 23, 25 and 71-75 are not rendered unpatentable over Panis *et al*, in view of Fretz *et al,* European Patent No. 0147236 and Goodrich *et al* (U.S. Patent No. 5,800,978), either alone or in combination. Applicant submits that there is no motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of Goodrich, Jr. *et al* or to combine the teachings of Goodrich, Jr. *et al* with the previously cited references, in order to reach the claimed invention.

Accordingly, Applicant submits that the claims are not obvious over Panis *et al*, in view of Fretz *et al*, European Patent No. 0147236 and Goodrich Jr., *et al* (U.S. Patent No. 5,800,978). Therefore, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 23, 25 and 71-75 under 35 U.S.C. § 103(a).

CONCLUSION

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested.

Respectfully submitted,

HUNTON & WILLIAMS LLP

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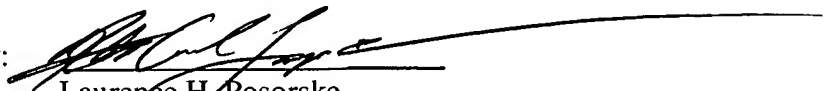
By: 

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